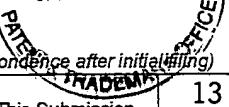


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Total Number of Pages in This Submission

13

Application Number	10/584,477
Filing Date	June 23, 2006
First Named Inventor	Thomas Hille
Art Unit	3743
Examiner Name	
Attorney Docket Number	R04283US (#90568)

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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Please charge any additional fees or credit any overpayment to Deposit Account No. 08-2441.		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	D. Peter Hochberg Co., L.P.A.		
Signature			
Printed name	D. Peter Hochberg		
Date	January 17, 2007	Reg. No.	24,603

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature		
Typed or printed name	Christine Kotran	Date
	01 / 17 / 2007	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thomas Hille et al.

Serial No.: 10/584,477

Filed: June 23, 2006 / Conf. No. 3321

Title: WOUND DRESSING AND ADHESIVE WOUND DRESSING
COMPRISING A VASOCONSTRICTIVE INGREDIENT, AND
PROCESSES FOR THE PRODUCTION THEREOF

Examiner: _____ / Art Unit: 3743

Attorney File: RO4283US (#90568)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-4150

L E T T E R

Sir:

Enclosed is a "Power of Attorney" which has been executed by both of the inventors to the undersigned and to Sean Mellino with instruction to send all correspondence to the undersigned. Entry on the records of the U.S. Patent and Trademark Office is earnestly solicited and confirmation hereof is respectfully requested.

Also enclosed for inclusion in the record of the referenced patent application is an English translation of the "International Preliminary Report on Patentability" as rendered with respect to PCT/EP2004/013996 from which this is a 371 application.

Respectfully submitted,

By: _____

D. Peter Hochberg
Reg. No. 24,603

DPH/SM/ck
Enc.

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I hereby certify that this document, and anything indicated as being attached or enclosed, is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date noted below.

Christine Kotran: Christine Kotran

Date: January 17, 2007

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

FLACCUS, Rolf-Dieter
Bussardweg 10
50389 Wesseling
ALLEMAGNE

Eingegangen

04. JAN. 2007

FRIST:.....

Date of mailing (day/month/year)
28 December 2006 (28.12.2006)

Applicant's or agent's file reference
LTS 2003/010 PCT

IMPORTANT NOTIFICATION

International application No.
PCT/EP2004/013996

International filing date (day/month/year)
09 December 2004 (09.12.2004)

Applicant

LTS LOHMANN THERAPIE-SYSTEME AG et al

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yolaine Cussac

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TRANSLATION PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2003/010 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/013996	International filing date (day/month/year) 09.12.2004	Priority date (day/month/year) 24.12.2003
International Patent Classification (IPC) or national classification and IPC A61L15/44		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>6</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>

Date of submission of the demand	Date of completion of this report <u>05.05.2006</u>
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/013996

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:

international search (Rule 12.3 and 23.1(b))
 publication of the international application (Rule 12.4)
 international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

the international application as originally filed/furnished
 the description:
 pages 1-14 _____ as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____

the claims:
 nos. _____ as originally filed/furnished
 nos.* _____ as amended (together with any statement) under Article 19
 nos.* 1-24 _____ received by this Authority on 14.10.2005 with letter
 nos.* _____ received by this Authority on _____

the drawings:
 sheets 1/1 _____ as originally filed/furnished
 sheets* _____ received by this Authority on _____
 sheets* _____ received by this Authority on _____

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (specify): _____
 any table(s) related to sequence listing (specify): _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (specify): _____
 any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/013996

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1 6-22	YES
	Claims	1-15, 23, 24	NO
Inventive step (IS)	Claims	1 6-22	YES
	Claims	1-15, 23, 24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. This report makes reference to the following documents:

D1: US 5 098 417 A (YAMAZAKI ET AL) (1992-03-24)
 D2: EP 0 338 173 A (RICOH KYOSAN, INC) (1989-10-25)
 D3: US 2003017970 A1 (RODGERS KATHLEEN E ET AL) (2003-01-23)

2. INDEPENDENT CLAIMS 1, 16, 23, 24

I) Novelty

The objections to the product and its use are upheld in their entirety.

The present application thus does not meet the requirements of PCT Article 33(1) because the subject matter of claims 1-15 and 23, 24 is not novel (PCT Article 33(2)).

2.1

Document D1 discloses a wound dressing with physiologically and biologically active agents, such as

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/013996

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

antibacterial, antifungal, analgesic, tissue-healing, local anaesthetic agents, as well as active substances for stopping bleeding, enzymes and vasoconstrictor substances (cf. column 7, lines 60-65).

The active vasoconstrictor substance can be selected from epinephrine (adrenaline) or serotonin (cf. column 9, lines 67, 68).

D1 further describes the additional features of a commercially available wound dressing, including the admixture of further skin-care substances, an additional active astringent substance, as well as the structure of a wound dressing comprising a substrate material based on a woven or knitted fabric, as well as the use of adhesives, adhesive layers, peelable protective layers, preservatives, etc. Consequently, D1 should be considered prejudicial to the novelty of the subject matter of claims 1-15, 23 and 24 (cf. PCT Article 33(1) and 33(2)).

2.2

Document D2 discloses a wound dressing for burns which, like the wound dressing in D1, contains active substances (see the above-mentioned active substances), in particular an active styptic substance, as well as an active vasoconstrictor substance, such as epinephrine (cf. page 3, lines 13-15, 43).

The inherent features of the dressing, such as substrate material, adhesive layer, etc. are described. The additional features of the structure of the dressing, as well as additional active substances, claimed in the

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/013996

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

present application, are features which are known to a person skilled in the art and therefore not novel.

The subject matter of claims 1-15, 23 and 24 of the present application should therefore not be considered novel (cf. PCT Article 33(1) and 33(2)).

3. DEPENDENT CLAIMS 2-9, 11-15, 17-22

Claims 2-9 do not contain any features which, in combination with the features of any claim to which they refer, meet the PCT novelty and inventive step requirements.

II) Inventive step

A subject matter which has already been deprived of novelty cannot be considered inventive, since it makes no contribution over the prior art (cf. PCT Article 33(1) and 33(3)).

The subject matter claimed in the present application relates to a wound dressing manufacturing process, as well as to the wound dressing itself, containing adrenaline or one of its pharmaceutically acceptable salts as active vasoconstrictor substance, and which can therefore quickly stop bleeding when applied to bleeding wounds.

The applicant mentions in the description that the use of adrenaline (epinephrine) in the form of an adrenaline solution applied by means of a cotton swab to fresh bleeding wounds is very well known in boxing sports for

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/013996

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

effectively causing the bleeding to stop.

The present invention therefore consists in the administration form as a wound dressing with adrenaline as active substance, and in the claimed production process.

The problem is adrenaline instability in the presence of atmospheric oxygen.

D3 has shown that active vasoconstrictor substances, such as angiotensine analogues, have already been effectively used in wound dressings, i.e. are already known.

Moreover, D1 and D2 have already disclosed the use of epinephrine (adrenaline) in wound dressings.

Consequently, an inventive step cannot be acknowledged in the claimed subject matter and claimed production process as per claims 16-22 (see EPC Articles 52 and 56).

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Prima facie, the invention according to the present application does not appear to relate to details of the wound dressing, since it comprises the structure, additives and materials which are customary in the prior art, but rather to process-relevant details which prevent the active vasoconstrictor substance adrenaline from being destroyed by atmospheric oxygen.

The examiner fully agrees with the objection put forth by the applicant's agent, according to which "none of the documents D1-D3 mentions measures for preventing adrenaline from decomposing in the wound dressing".

Nevertheless, it is not possible to recognise in the wound dressing as per claims 1-15 and in its use as per claim 24 any features which, in comparison with the prior art documents D1-D3, counteract "adrenaline decomposition".

Consequently, the subject matter of claims 1-15, 23 and 24 is drafted as the expression of a wish, of a desirable result.

In view of the applicant's explanations, it appears absolutely necessary to claim the product in terms of a "product-by-process" claim.

Moreover, it is not possible to recognise from the present description to what extent the structural or physico-chemical features of the wound dressing solve the

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/013996

Box No. VIII Certain observations on the international application

adrenaline instability problem in its use as a wound dressing for daily use (cf. present application, pages 1-3).